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[REDACTED] EXAMINER

ROARK, JESSICA H

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/940,063             | BRISKIN ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Jessica H. Roark       | 1644                |  |

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 13 June 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 16,21-47,53,60,84,88 and 97-115 is/are pending in the application.
- 4a) Of the above claim(s) 16,47,53,60 and 115 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-46,84,88 and 97-114 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 August 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

1. Applicant's amendment, filed 6/13/03 (Paper No. 10), is acknowledged.

Claims 51, 58, 67, 69, 77, 80 and 89-94 have been canceled.

Claims 1-15, 17-20, 48-50, 52, 54-57, 59, 61-66, 68, 70-76, 78-79, 81-83, 85-87 and 95-96 have been canceled previously.

Claims 113-115 have been added.

Claims 16, 24-26, 35-37, 47, 53 and 60 have been amended.

*Claims 16, 21-47, 53, 60, 84, 88 and 97-115 are pending.*

2. Applicant's election of Group III in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claim 115 is directed to the subject matter of Group IV set forth in Paper No. 9 for the reasons set forth in Paper No. 9 with respect to Group IV.

Applicant's request for rejoinder of claims 16, 47, 53, 60 and newly added claim 115 in accordance with MPEP 821.04 is acknowledged. However, in view of the rejections set forth with respect to product claim 21, rejoinder is held in abeyance.

Claims 16, 47, 53, 60 and 115 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

*Claims 21-46, 84, 88 and 97-114 are under consideration in the instant application.*

## IDS

3. Applicant's IDS, filed 8/27/01 (Paper No. 7), is acknowledged.

## *Drawings*

4. The formal drawings submitted 8/27/01 are acceptable.

## *Specification*

5. Applicant is requested to avoid the use of novel in the title, as patents are presumed to be novel and unobvious.

6. The abstract of the disclosure is objected to because it appears to be longer than 150 words in length. Correction is required. See MPEP § 608.01(b).

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

***Priority***

8. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. Applicant is requested to update the priority claim to reflect that USSN 09/449,437 is now U.S. Pat. No. 6,319,675.

***Claim Objections***

9. Claims 27 and 110 are objected to under 37 CFR 1.75 as being substantial duplicates of one another.

Although claim 27 recites that the binding is to Bonzo and claim 110 recites that the binding is to mammalian Bonzo, both claims depend from claim 21, which recites mammalian Bonzo.

10. Claim 27 is objected to because of the following informalities: it appears a semicolon rather than a comma is needed following the ATCC Accession Number PTA-991 and ATCC Accession Number PTA-992, as found in claim 103. Appropriate correction is required.

***Claim Rejections - 35 USC § 112 second paragraph***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

12. Claims 23, 39 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 39 and 46 are indefinite in that they describe the product of interest by an arbitrary protein name, "SExCkine". The instant recitation fails to distinctly claim what this protein is. For example, others in the field may isolate the same protein and give it an entirely different name.

Applicant should particularly point out and distinctly claim "SExCkine" by claiming a sufficient number of characteristics associated with the protein or its amino acid sequence.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

13. It is noted that Bonzo was an art-recognized name for a particular 7 transmembrane spanning protein known to be a co-receptor for both SIV and HIV-1, although the protein was also known in the art as HBMBU14, TYMSTR and STRL33. See e.g. WO99/50670 (IDS #AL) at page 3. In addition, the amino acid sequence for Bonzo proteins from human, African green monkey, pigtail macaque and chimpanzee were known in the art at the time the invention was made. See WO99/03888 (IDS #AN) and Brussel et al. (AIDS Res Hum Retroviruses. 1999 Sep 20;15(14):1315-1319).

***Claim Rejections - 35 USC § 112 first paragraph***

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

15. Claims 21-22, 24-27, 34-38, 40-45, 84, 88 and 97-114 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

Independent claims 21, 34 and 41, and claims depending therefrom, recite an antibody or a cell line producing an antibody, wherein the antibody inhibits the binding of a ligand to Bonzo, or a cellular response to binding of a ligand, as part of the invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3<sup>rd</sup> column).

However, there does not appear to be an adequate written description in the specification as-filed of any essential structural feature common to molecules that are "ligands that bind Bonzo" that identifies molecules as having the function of binding Bonzo. The specification discloses chemokine ligands of Bonzo that are SExCkine and PF4 (e.g., page 27 at line 17). However, the genus of molecules encompassed by the term "ligand" is very large and includes highly diverse molecules that are not only chemokines, but also any molecule or pathogen which has the function of binding Bonzo. Thus the disclosure of two species of ligands does not appear to provide an adequate written description of the extensive genus of molecules which are "ligands that bind Bonzo".

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

16. In claims 27-33, 88, 103-108 and 110-112, it is apparent that the cell lines producing antibodies 4A11, 7A2 and 7F3 are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

It is noted that page 32 of the specification at lines 10-28 (as amended 8/17/01) indicates that these cell lines were deposited with the ATCC on November 24, 1999. In addition, Applicant has assured in Paper No. 11 (filed 8/27/01) that all restrictions will be irrevocably removed upon granting of a patent and that the deposits were made under the terms of the Budapest Treaty.

Therefore, the enablement requirement under 35 USC 112, first paragraph is considered to be fulfilled.

***Claim Rejections – 35 U.S.C. §§ 102 and 103***

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

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18. Claims 21-27, 34-46 and 103-114 are rejected under 35 U.S.C. 102(a) as being anticipated by Catalog #MAB699 (STRL 33/Bonzo Monoclonal antibody, *de novo*, New Products from R&D Systems, p.7 (April 1999), IDS #AY4), as evidenced by the Monoclonal Anti-human STRL 33/Bonzo Antibody Technical Information, R&D Systems, Inc. (5/10/1999), IDS # AZ4 and the instant specification in Figure 32 and in the Figure 32 legend on page 13 at lines 12-18.

Catalog #MAB699 teaches a monoclonal antibody that binds human Bonzo. The Technical Information provides evidence that both a monoclonal antibody that binds human Bonzo and hybridoma 56811.111 producing this monoclonal antibody were known or used by others in this country, and described in a printed publication in this country, before the invention thereof by Applicant (see entire Technical Information sheet).

Both the Catalog entry and the Technical Information sheet are silent as to functional properties of the monoclonal antibody to human Bonzo.

However, Figure 32 of the instant specification, as described in the Figure legend on page 13 at lines 12-18, shows that MAB699 inhibits SExCkine-induced chemotaxis of Bonzo/L1.2 cells.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. Since MAB699 binds Bonzo and inhibits chemotaxis in response to the Bonzo ligand SExCkine, the instantly recited properties of inhibition of SExCkine binding and inhibition of signal transduction or the various cellular responses such as Ca flux that are recited would be inherent properties of MAB699. Further, one or more of the deposited mAbs 4A11, 7A2 and 7F3 would necessarily inhibit, at least to some degree, the binding of MAB699. Finally, in view of the functional properties of MAB699, MAB699 appears to have the same epitopic specificity as mAbs 4A11, 7A2 and 7F3.

It is acknowledged that the legend to Figure 32 indicates that in this particular set of conditions MAB699 only inhibits the in vitro chemotaxis assay with an IC<sub>50</sub> of 7.97 µg/mL, while certain of the claims included in the instant rejection require inhibition of less than about 7 µg/mL. However, the phrase "less than about" clearly opens the claims up to values near 7. In addition, other assays are encompassed by the claim language, and the IC<sub>50</sub> of MAB699 in at least one of these other assays would inherently be less than about 7 µg/mL. Finally, an IC<sub>50</sub> of less than about 7 µg/mL is close to the value shown in Figure 32 that if the value of 7.97 µg/mL would necessarily be within the experimental error.

Applicant is reminded that "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F. 2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). See MPEP 2112.

The reference teachings thus anticipate the instant claimed invention.

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19. Claims 21-22, 24-27, 34-38, 40-45, 97-102, 109-114 are rejected under 35 U.S.C. 102(a) as being anticipated by MacPhee et al. (WO 99/50670, IDS #AL, see entire document).

MacPhee et al. teach that platelet factor 4 (PF-4) binds a PF-4 receptor that is the same as human Bonzo (see entire document, e.g., Abstract and pages 3-5, especially page 5 at lines 6-10). MacPhee et al. teach that in response to binding of the ligand PF-4, the PF-4 receptor Bonzo on the surface of a cell results in cellular responses including chemotaxis, calcium flux, and the transduction of various other signals into the cell (see pages 6-7 and 15-19). MacPhee teaches that assays which detect these signals can be used to assay for inhibitors (e.g., pages 6-7 and 15-19).

MacPhee et al. teach that antibodies can be produced which neutralize receptor function and the cell lines producing these antibodies can be isolated (e.g., page 9).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of an antibody which bound human Bonzo and neutralized binding of PF-4.

In particular, although the reference does not appear to teach what minimum IC<sub>50</sub> values the neutralizing antibodies should have, an antibody that is characterized as "neutralizing" would necessarily have an IC<sub>50</sub> of less than about 1 µg/mL.

Further, an antibody that neutralize binding of PF-4 to Bonzo would inherently be inhibited to at least some degree by the binding of one or more of deposited antibodies 4A11, 7A2 or 7F3.

Applicant is reminded that "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F. 2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). See MPEP 2112.

The reference teachings thus anticipate the instant claimed invention.

20. Claims 21-22, 34, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Farber et al. (WO 98/44098, IDS #AP, see entire document).

Farber et al. teach that the human STRL33 protein is bound by HIV as part of the entry of HIV into cells (see entire document, e.g., "Summary of the Invention" on pages 3-5). Thus HIV is a ligand of human STRL33. STRL33 is human Bonzo, as shown by the amino acid sequence presented in Figure 4.

Farber et al. teach antibodies and antibody fragments which bind STRL33 and block membrane fusion between HIV and a target cell (see e.g., page 4 at lines 5-7 and pages 26-33). Farber et al. also teach the cell lines, including hybridomas, which produce these antibodies (e.g., page 29).

The reference teachings thus anticipate the instant claimed invention.

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21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 84 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catalog #MAB699 (STRL 33/Bonzo Monoclonal antibody, *de novo*, New Products from R&D Systems, p.7 (April 1999), IDS #AY4), as evidenced by the Monoclonal Anti-human STRL 33/Bonzo Antibody Technical Information, R&D Systems, Inc. (5/10/1999), IDS # AZ4 and the instant specification in Figure 32 and in the Figure 32 legend on page 13 at lines 12-18, in view of Jardieu et al. (US Pat. No. 6,037,454).

The claims are drawn to a test kit for detecting the presence of Bonzo in a biological sample comprising an antibody which binds Bonzo and inhibits binding of a ligand, and one or more ancillary reagents suitable for detecting the antibody-Bonzo complex, including wherein the antibody competes with mAb 4A11, mAb 7A2 or mAb 7F3.

The teachings of catalog #MAB699 have been discussed in detail *supra*.

The Anti-human STRL 33/Bonzo Antibody Technical Information teaches that the antibody may be used in flow cytometry to detect human STRL33 (see "Application").

Neither Catalog #MAB699 nor the Technical Information teaches the antibody in a test kit comprising one or more ancillary reagents suitable for detecting the antibody-Bonzo complex.

However, the formulation of antibodies that detect receptors expressed on the surface of a cell into a kit comprising ancillary agents for the detection of the antibody-receptor complex would have been obvious to the ordinary artisan at the time the invention was made in view of any teaching of the antibody, but particularly in view of a teaching to use the antibody in a detection assay.

For example, Jardieu et al. teach antibodies to another cell surface receptor, CD11A (see entire document). Jardieu et al. teach that antibodies can be used in numerous diagnostic assays to detect proteins and that many different agents were available for detecting the antibody bound to its antigen (see e.g. columns 28-30). Jardieu et al. also teach that as a matter of convenience, antibodies and ancillary agents for detecting the binding of the antibody to the target antigen may be packaged together in a kit (see column 30, especially lines 19-34).

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It therefore would have been obvious to the ordinary artisan at the time the invention was made to combine MAB699 with one or more ancillary agents for detecting the antibody in complex with Bonzo. The ordinary artisan at the time the invention was made would have been motivated to provide the antibody in kit as a matter of convenience, as taught by Jardieu et al. Given the teaching of MAB699 and its applicability in detection assay, and the teachings of Jardieu et al regarding the numerous ancillary reagents available, the ordinary artisan would have had a reasonable expectation of formulating the antibody in a kit with more or more ancillary reagents. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

23. Claims 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacPhee et al. (WO 99/50670, IDS #AL).

The claim is drawn to a test kit for detecting the presence of Bonzo in a biological sample comprising an antibody which binds Bonzo and inhibits binding of a ligand, and one or more ancillary reagents suitable for detecting the antibody-Bonzo complex.

The teachings of MacPhee et al. have been discussed in detail *supra*.

MacPhee et al. do teach an antibody to PF4 receptor/Bonzo in a test kit comprising one or more ancillary reagents suitable for detecting the antibody-Bonzo complex.

However, the formulation of antibodies that detect receptors expressed on the surface of a cell into a kit comprising ancillary agents for the detection of the antibody-receptor complex would have been obvious to the ordinary artisan at the time the invention was made in view of any teaching of the antibody.

For example, Jardieu et al. teach antibodies to another cell surface receptor, CD11A (see entire document). Jardieu et al. teach that antibodies can be used in numerous diagnostic assays to detect proteins and that many different agents were available for detecting the antibody bound to its antigen (see e.g. columns 28-30). Jardieu et al. also teach that as a matter of convenience, antibodies and ancillary agents for detecting the binding of the antibody to the target antigen may be packaged together in a kit (see column 30, especially lines 19-34).

It therefore would have been obvious to the ordinary artisan at the time the invention was made to combine the anti-PF4 receptor/Bonzo antibody of MacPhee et al. with one or more ancillary agents for detecting the antibody in complex with Bonzo. The ordinary artisan at the time the invention was made would have been motivated to provide the antibody in kit as a matter of convenience, as taught by Jardieu et al. Given the teaching of MacPhee et al. of the anti-PF4 receptor/Bonzo antibody, and the teachings of Jardieu et al regarding the numerous ancillary reagents available, the ordinary artisan would have had a reasonable expectation of formulating the antibody in a kit with more or more ancillary reagents.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Double Patenting***

24. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

25. Claims 21 and 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 21 and 34 of copending Application No. 10/174,293. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 21-46, 84, 88 and 97-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 28, 31, 34, 90, 197-201, 203 and 205-206 of copending Application No. 10/174,293. Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibodies, cells producing and kits comprising are either the same species as recited in the instant claims, are species that anticipate the instantly claimed genus of antibodies and cells, or recite a genus in which an instantly claimed species is an obvious embodiment.

*This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.*

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***Conclusion***

28. No claim is allowed.
29. Claims 28-33 would appear to be allowable if the conflicting claims in USSN 10/174293 were cancelled as the prior art does not teach or suggest the particular species of antibodies and cell lines producing.
30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for before Final submissions is (703) 872-9306.

Jessica Roark, Ph.D.  
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September 15, 2003

PHILLIP GAMBEL  
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TECH CENTER 1600  
9/21/03